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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,761	07/10/2003	Benjamin N. Loomis	BBM-100US	2306
23122	7590	01/09/2006	EXAMINER	
RATNERPRESTIA			REICHLE, KARIN M	
P O BOX 980			ART UNIT	
VALLEY FORGE, PA 19482-0980			PAPER NUMBER	
			3761	
DATE MAILED: 01/09/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Tate

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/616,761	LOOMIS, BENJAMIN N.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Karin M. Reichle	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 July 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7-10-03</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed 7-10-03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The information referred to therein which was accompanied by a copy was considered. Since no copy of 365,969 nor the Vagifem reference are part of the electronic application nor readily available to the Examiner such have not been considered. If the Applicant provides copies thereof as well as evidence of their filing prior to this action, the references will be considered with the next response, if any. Otherwise, Applicant is advised that the date of any re-submission of such missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

### ***Specification***

#### ***Drawings***

2. The drawings are objected to because the labeling of Figures 8A-C and the description thereof on page 5, lines 1, 4, and 7, i.e. "8a", "8b" and "8c", are inconsistent. In Figure 7, 52 does not appear to denote a track as described in the paragraph bridging pages 7-8. Also, the tabs 54 are not shown accurately, i.e. on the side, not the top as described. Corrected drawing

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sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Description*

3. The disclosure is objected to because of the following informalities: 1) On page 3, lines 19-20 it is unclear what the structure of the side aperture is being defined, i.e. on line 19, should “joining the head of and” be deleted and on line 20, after “passage”, should --at the head of the barrel--? This also applies similar language in the abstract, and on page 5, lines 25-26. 2) As also discussed *infra*, does the dispenser include the suppository, i.e. see page 3, line 23, i.e. “a suppository is ejected”, or not, i.e. see page 3, line 14, i.e. “for delivering a”? If the former, “ejected” should be --ejectable-- and if the latter, “for delivering” should be --which delivers--.

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Note the discussion infra and that the Summary of the Invention section is a description of the invention of the claims and should be commensurate therewith, see MPEP 608.01(d). 3) On page 4, line 14 and page 5, line 16, should “undepressed” be --compressed--? On lines 16 and 18, should “inserted” and “depressed” be --relaxed-- and --compressed--, respectively? On page 5, lines 1, 4 and 7, page 7, line 15, page 9, lines 2 and 30 and page 10, lines 2, 8 and 12, should “a”, “b” and “c” be --A--, --B-- and --C--, respectively? See discussion of Figures supra. On page 5, lines 13 and 14, “drawing” should be --drawings--. 4) Does the nose 42 include protrusion 50, see page 6, lines 5-7 or does the protrusion extend from the nose, see page 9, lines 16-17? It is noted that the common dictionary definition of “nose” is “the forward end or projection of something”, i.e. the nose 42 is the forward end of the plunger. See also claims 3-5 and claims 12 and 19.

Appropriate correction is required.

### ***Claim Objections***

4. Claims 1-20 are objected to because of the following informalities: In claim 1, lines 11-12, after “position”, --upon actuation-- should be inserted, after “which a”, --compressed position the-- should be inserted and “, upon actuation” should be deleted. In claim 2, line 3, “a” should be --the--. In claim 3, as discussed supra, should “plunger...nose” be --the nose including a resilient folding protrusion--? Note claims 12 and 19. With regard to claims 12-20, see discussion of claims 1-11 which discussion also applies to similar language in these claims.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 1-11, it is unclear whether a suppository is being claimed, e.g. lines 11-12 of claim 1 and claim 3, or not, e.g. the preamble of claim 1 and claim 2. If so, a clear positive antecedent basis for such should be set forth and if not, e.g., on line 12 of claim 1, “ejected” should be --ejectable--. Also as discussed supra, the structure of the side aperture on lines 6-8 is unclear, see suggested language supra. Finally, on lines 10-12, is it being claimed that the plunger ejects the suppository from the side aperture in the compressed position or not? Note claims 3-5. In claims 9 and 11, are the inner surface of the body and the inside walls of the body and the surface of the passage one and the same, i.e. at a minimum how many walls or surfaces are being claimed? If they are not the same, a clear antecedent basis for “the inner surface of its body” in claim 9 and “the inside walls of the body” in claim 11 should be set forth. If so, “the inner surface of its body” in claim 9 could be amended as --the surface of the axial passage-- and “the inside walls of the body of the barrel” in claim 11 could be amended as --the surface of the axial passage--. With regard to claims 12-20, see discussion of claims 1-11 which discussion applies to similar language in these claims.

***Claim Language Interpretation***

6. Since Applicant has not set forth any explicit definition of the claim terminology, such will be interpreted according to its usual, i.e. dictionary, definition. Therefore, “suppository” is

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interpreted to as “a solid but readily meltable” “medicated material for insertion into a bodily passage or cavity”. “Barrel” is interpreted as “a cylindrical part”. “Proximate” is interpreted as “very near, close”. With regard to “nose, see discussion supra. Due to the lack of clarity discussed supra, claims 1, 12 and 19 are interpreted as including a suppository, a side aperture providing external access through the body of the barrel to the axial passage at the head of the barrel and a plunger which ejects the suppository in its compressed position.

***Allowable Subject Matter***

7. The prior art references, alone or in any combination, do not teach a dispenser which delivers a suppository, i.e. includes the suppository, within a body cavity which comprises a barrel, i.e. cylinder, having a head, a foot, and a body having a length and extending between the head and foot, the barrel defining an axial passage disposed along substantially the entire length of the body beginning at the foot and ending close to the head and the barrel including a side aperture providing external access through the body to the axial passage at the head thereof and a plunger including a nose, a tail, a frame extending therebetween, and a length sized to travel within the axial passage of the barrel between a relaxed position and a compressed position when actuated and the plunger ejecting the suppository from the side aperture in the compressed position as best understood is claimed in claim 1, see discussion supra, or such in combination with the other structure claimed in claims 12 and 19.

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*Conclusion*

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied art show various dispensers.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Karin M. Reichle  
Primary Examiner  
Art Unit 3761

KMR  
January 3, 2006